MAY 2 8 2004

510(k)-KOLPEXIN* Sphere – New Device

510(k) SUMMARY

KOLPEXIN* Sphere
(Indication for management of vaginal prolapse and pelvic floor muscular weakness)

1. DATE PREPARED

August 20, 2003

2. SUBMITTER

ADAMED Ltd.
Pienkow 149, 05-152 Czosnow
Poland

3. CONTACT

Norman I. Bruckner, (972)596-4151
Study Manager, Consultant

4. NAME OF THE MEDICAL DEVICE

Classification name:	Vaginal Weight/Vaginal Pessary
Common/Usual Name:	Training Aid for Pelvic Floor Muscle or Kegel Exercise and Pessary for Vaginal Prolapse
Proprietary name:	KOLPEXIN* Sphere

5. DEVICE CLASSIFICATION

The KOLPEXIN* Sphere has been classified by the FDA under the headings of Perineometer HIR and Vaginal Pessary HHW, both Class II devices.

6. STATEMENT OF SUBSTANTIAL EQUIVALENCE

KOLPEXIN* Sphere with indications for conservative management of vaginal prolapse and pelvic floor muscular weakness in females is substantially equivalent in function to weighted vaginal training aids for the pelvic floor muscle or Kegel exercise and Gellhorn pessary both marketed by Milex Products, Inc.
*Trademark

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7. INDICATIONS FOR USE

The KOLPEXIN* Sphere is indicated for the conservative management of vaginal prolapse and pelvic floor muscular weakness.

8. PHYSICAL DESCRIPTION

The KOLPEXIN* Sphere is symmetrically circular shaped with an attached nylon string for device removal. The device is made from medical grade polycarbonate, LEXAN 144R-111, GE Plastics, and is available in six sizes; 44mm, 42mm, 39mm, 36mm, 32mm and 28mm.

9. BIOCOMPATIBILITY TESTING

Materials manufacturer safety tests demonstrate that the KOLPEXIN* Sphere is non-sensitizing, non-irritating and suitable for its intended use.

10. CLINICAL STUDY

A multicenter study to confirm the safety, efficacy, and functionality of the KOLPEXIN* Sphere in women with vaginal prolapse was performed. The study was entitled "A Multicenter Evaluation of the COLPEXIN* Vaginal Sphere in Females with Vaginal Prolapse."

The study concluded the KOLPEXIN* Sphere is a safe and effective device for the conservative management of vaginal prolapse and pelvic floor muscular weakness.

*Trademark

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 8 2004

Adamed Ltd.
c/o Norman I. Bruckner, Ph.D.
Study Manager, Consultant
Bruckner & Associates, LLC.
3432 Brookshire Drive
PLANO TX 75075

Re: K032644
Trade/Device Name: KOLPEXIN™ Sphere
Regulation Number: 21 CFR 884.3575
Regulation Name: Vaginal Pessary
Regulatory Class: II
Product Code: 85 HHW
Dated: February 25, 2004
Received: March 1, 2004

Dear Dr. Bruckner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k032644

Device Name: KOLPEXIN™ Sphere

Indications For Use:

The KOLPEXIN™ Sphere is a vaginal pessary that is indicated for the conservative management of vaginal prolapse and pelvic floor muscular weakness.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) ~~AND~~/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David R. Lynn

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032644